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General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela GentleLASE Family of Laser Systems, which is substantially equivalent to previously marketed devices . The GentleLASE Family of lasers is indicated for use for the treatment of wrinkles.

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	William H. McGrail
Date prepared:	December 26, 2002
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Common Name:	Dermatology Laser, GentleLASE Family of Laser Systems
Predicate Devices:	Candela GentleLASE GL (K994260)

Description:

The Candela GentleLASE Family of Lasers utilizes an Alexandrite rod (crystal) which emits pulsed energy at 755 nanometers in the near infrared region. Energy from the laser is directed to the target area via optical fiber/handpiece delivery system. The Dynamic Cooling Device, which provides a short burst of cryogen spray prior to firing the laser pulse. The laser output energy is delivered via an optical fiber to a handpiece, which produces a circular beam on the skin. The cryogen, which is housed within the laser enclosure, is delivered via a hose to a nozzle located in the handpiece. The GentleLASE Family of Laser Systems are designed with six major components:

1. High voltage power supply and modulator system
2. Optical laser head
3. Circulator system
4. Optical delivery system
5. Software control system
6. Dynamic cooling device

The Candela GentleLASE Family of Laser Systems are equipped with safety interlock systems to protect patients and operators. Users of the device make selections from an onboard control panel to regulate operation during treatment.

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Testing:

As laser products, the GentleLASE Family of laser Systems are required to conform and does conform to the Laser Performance Standard (21 CFR 1040). In addition the GentleLASE Family of Laser Systems conforms to the UL 2601 Electrical Safety Standard and with the Harmonized Standard EN 60601-1-2, Part 2 established by and required by the European Community.

Safety and Effectiveness Information:

The indications for use for the treatment of wrinkles is based on a controlled clinical study using a device that has been cleared for use in the market. We therefore believe that there are no questions of safety or effectiveness raised by the introduction of the Candela GentleLASE Family of Laser Systems.

Summary of Substantial Equivalence:

The Candela GentleLASE Family of Laser Systems have the same intended use, utilizes similar operating principles and matches key design aspects, including similar spot size, the same wavelength and the same maximum delivered fluence as the predicate device.

On the basis of similarities in methods of assembly, method of operation, and intended uses, Candela Corporation believes that the Candela GentleLASE Family of Laser Systems is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 2003

Mr. William H. McGrail
Vice President Research & Development
and Operations
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K024335
Trade/Device Name: GentleLASE Family of Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 26, 2002
Received: December 27, 2002

Dear Mr. McGrail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CANDELA

INDICATION FOR USE STATEMENT

510(k) Number (if known): K024335

Device Names Candela GentleLASE Family of Laser Systems

Indications For Use:

1. Treatment of Wrinkles

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024335